Mountainside Hospital
ATLANTIC HEALTH SYSTEM

Sandra Gabriel
Health Physicist
U.S.N.R.C.
Division of Nuclear Materials Safety
Region I
475 Allendale Road
King of Prussia, PA 19406

RE: License Number 29-03297-02

03002470

February 24, 2006

Dear Ms. Gabriel,

Since 1993, Mountainside hospital has successfully treated patients with a Nucletron Classic HDR system. We are now scheduled to upgrade this unit to a V2 (version 2) system sometime in May of this year (probably during our next quarterly source exchange).

We therefore will need to replace the Nucletron HDR afterloader model and corresponding source model currently installed at our facility and listed on our materials license. The HDR source and afterloader should be amended as follows:

Source Description:	Iridium-192 Sealed Source Nucletron, Model 105.002
Maximum Activity/Number of sources:	Two sources up to 12 Curies each
Device Description:	Nucletron microSelectron HDR Model 105.999

The sealed source and device registries which support the above source and device are MD-0497-S-107-S and MD-0497-D-108-S. Please see enclosures for supporting documentation.

If you have need of any further information, please do not hesitate to contact Robert Sasso at 973-429-6099 or at robert.sasso@ahsys.org.

Thank you for your kind attention in this matter.

Yours Truly,

Lydia N. Tarta
Director, Oncology Services

cc: Robert Sasso, RSO

138529

1 Bay Avenue, Montclair, New Jersey 07042 (973) 429-6000

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SOURCE
(AMENDED IN ITS ENTIRETY)

NO: MD-0497-S-107-S DATE: May 19, 2004

SOURCE TYPE: Medical Gamma Afterloading Source

MODEL: 105.002 (formerly DRN 07736)

DISTRIBUTOR: Nucletron Corporation
8671 Robert Fulton Drive
Columbia, Maryland 21046

MANUFACTURER: Mallinckrodt Medical B.V.
Westerduinweg 3
NL-1755 LE Petten
The Netherlands
OR
AEA Technology
40 North Avenue
Burlington, Massachusetts

ISOTOPE: Iridium-192

MAXIMUM ACTIVITY: 12 curies (444 GBq) **installed. 13 curies (481 GBq) replacement source to decay at facility**

LEAK TEST FREQUENCY: Six (6) months

PRINCIPAL USE: (V) General Medical Use

CUSTOM SOURCE: Yes___ No_X_

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SOURCE
(AMENDED IN ITS ENTIRETY)

SOURCE TYPE: Medical Gamma Afterloading Source

DESCRIPTION:

The source is constructed of iridium-192 metal [source pellet dimensions 0.65 millimeters (mm) diameter, 3.6-mm length], which is single encapsulated in a stainless steel (AISI 316L) cylindrical capsule (capsule dimensions 0.9 mm diameter, 4.5 mm length). The source is at one side hemispherical and the other side welded to a metal plug and stainless steel flexible cable. At the other end of the cable a metal engraved tail is welded. The source cable is 2018 mm in length and consists of two sections. The first section is 1868 mm in length and 0.9 mm diameter with 19 strands of wire that are right crosslaid. A second section of more flexible cable has been welded to the distal end of the source cable and is 150 mm in length and 0.72 mm in diameter consisting of 7 strands of 7 stranded wire rope that is also crosslaid.

LABELING:

The source tail end-piece is engraved with a unique serial number and marked with a color code for type recognition.

DIAGRAMS:

See attachments I & II with detail drawings.

CONDITIONS OF NORMAL USE:

Sources will only be used in conjunction with model 105.999 (Nucletron Corporation MicroSelectron-HDR Version 2). Information pertaining to the operation and handling of the source in conjunction with the above device can be found in the Sealed Source and Device Sheet MD-0497-D-108-S.

SOURCE TYPE: Medical Gamma Afterloading Source

PROTOTYPE TESTING:

Mallinckrodt Medical B.V. and AEA Technology, Inc. have tested the sources in accordance with ISO 2919 and ISO 1677 requirements. The testing was conducted under the consultation of the Ministry of Medical Investigation and Testing (BAM) located in Berlin, Germany. The source achieved to classification designation ISO/C53211. This rating is comparable to model DRN 07735 (source formerly registered as CI L BV) in the MicroSelectron-HDR Classic. The cable portion of source was tested to withstand a curve (radius $\geq$ 30 mm) without permanent deformation and 150 mm from the cable part at the source side distal end must withstand a curve (radius $\geq$ 15 mm) without permanent deformation. The cable tensile strength is > 200 Newton (N).

EXTERNAL RADIATION LEVELS:

For 12-curie source: DOSE RATE IN AIR

5 Centimeters	30 Centimeters	100 Centimeters
2,300 R/hr	64 R/r	5.76 R/hr

QUALITY ASSURANCE AND CONTROL:

In addition to Mallinckrodt and AEA Technology's regular quality control checks, all source welds are visually checked for weld sufficiency and all welded connections are mechanically tested by a pull test of 15 N of force for up to three (3) minutes. All sources are leak tested prior to shipment.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SOURCE
(AMENDED IN ITS ENTIRETY)

NO: MD-0497-S-107-S DATE: May 19, 2004 PAGE 4 OF 7

SOURCE TYPE: Medical Gamma Afterloading Source

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

1. The source shall be distributed only to persons specifically licensed by the U.S. Nuclear Regulatory Commission (NRC) or an Agreement State.

2. The source shall be leak tested at (6) month intervals using techniques capable of detecting 0.005 microcurie of removable contamination.

3. The source shall not be subjected to environmental or other conditions of use which exceed the ISO/C53211 classification.

4. **The Nucletron Corporation model 105.002 sealed source is manufactured by Mallinckrodt Medical BV, Petten, Holland, and AEA Technologies, Inc. Burlington, MA. exclusively for use in the Nucletron model 105.999 remote gamma afterloading brachtherapy device.**

5. Handling, storage, use, transfer and disposal is to be determined by the licensing authority. Since these sources exhibit high surface dose rates when unshielded, the sources should be handled only by experienced licensed personnel using adequate remote handling equipment and procedures.

6. This registration sheet and the information contained with the references shall not be changed or transferred without written consent of the Maryland Department of the Environment-Radiological Health Program.

SAFETY ANALYSIS SUMMARY:
Based on our review of the information and data submitted, we conclude that the model 105.002 (formerly DRN 07736) source is acceptable for licensing purposes. We conclude that this source would be expected to maintain its containment integrity for normal and accidental conditions which might occur during routine use.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SOURCE
(AMENDED IN ITS ENTIRETY)

NO: MD-0497-S-107-S DATE: May 19, 2004

SOURCE TYPE: Medical Gamma Afterloading Source

REFERENCES:

The following supporting documents for the **Model 105.002** (formerly DRN 07736) source are hereby made part of this registry document:

1. The Nucletron Corporation application for evaluation received October 4, 1996; letters with attachments dated November 20, 1996, and November 26, 1996
2. Letters and attachments dated February 6, 1997, July 20, 1998, March 25, 1999, April 22, 2000, and November 3, 2000.
3. Letter dated December 27, 2001, requesting model number change, letter dated April 22, 2003 changing the distribution address, and letter with attachments dated July 14, 2003, adding a new source manufacturer.
4. **Letter received from Nucletron Corporation on August 4, 2003, with BAM Approval Certificate D/0070/S-96 (Rev. 2), which adds AEA Technology as a manufacturer of this source.**

DATE: May 19, 2004 REVIEWED BY: Barbara J. Park
Barbara J. Park

DATE: May 19, 2004 CONCURRENCE: Raymond E. Manley
Raymond E. Manley

ISSUING AGENCY:

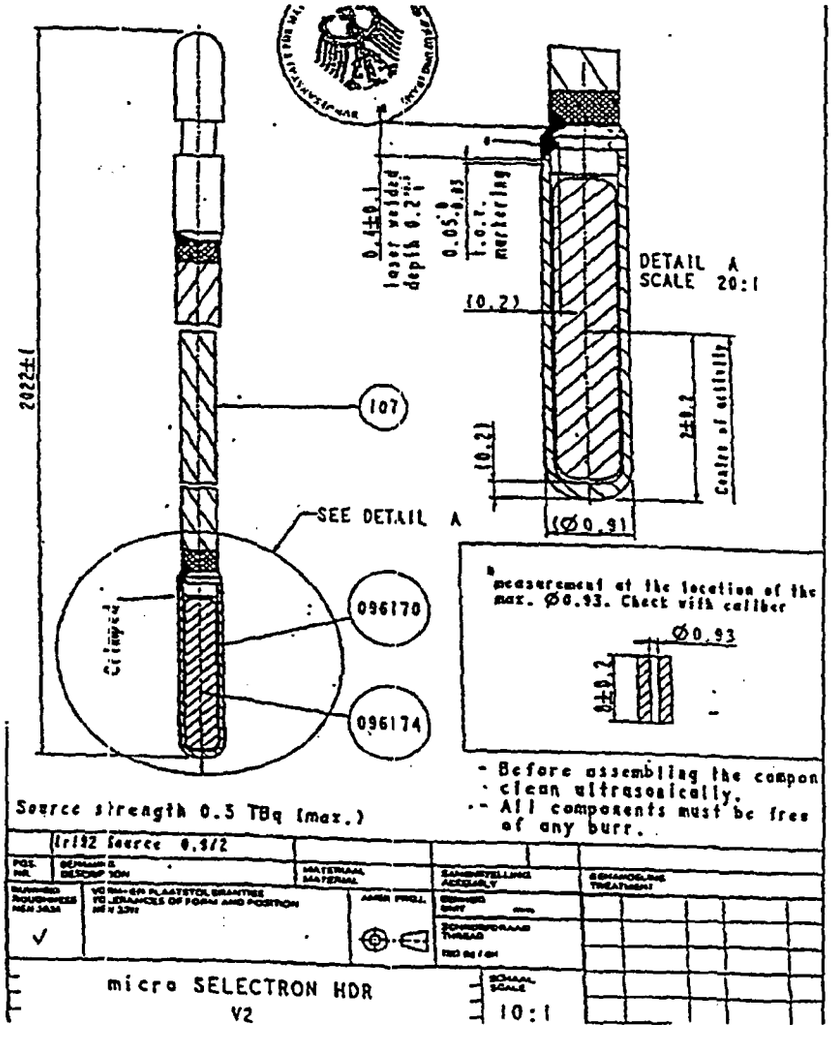
Maryland Department of the Environment
Radiological Health Program
1800 Washington Boulevard, Suite 750
Baltimore, Maryland 21230

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SOURCE
(AMENDED IN ITS ENTIRETY)

NO: MD-0497-S-107-S DATE: May 19, 2004 PAGE 6 OF 7

SOURCE TYPE: Medical Gamma Afterloading Source

Attachment 1 Source Detail

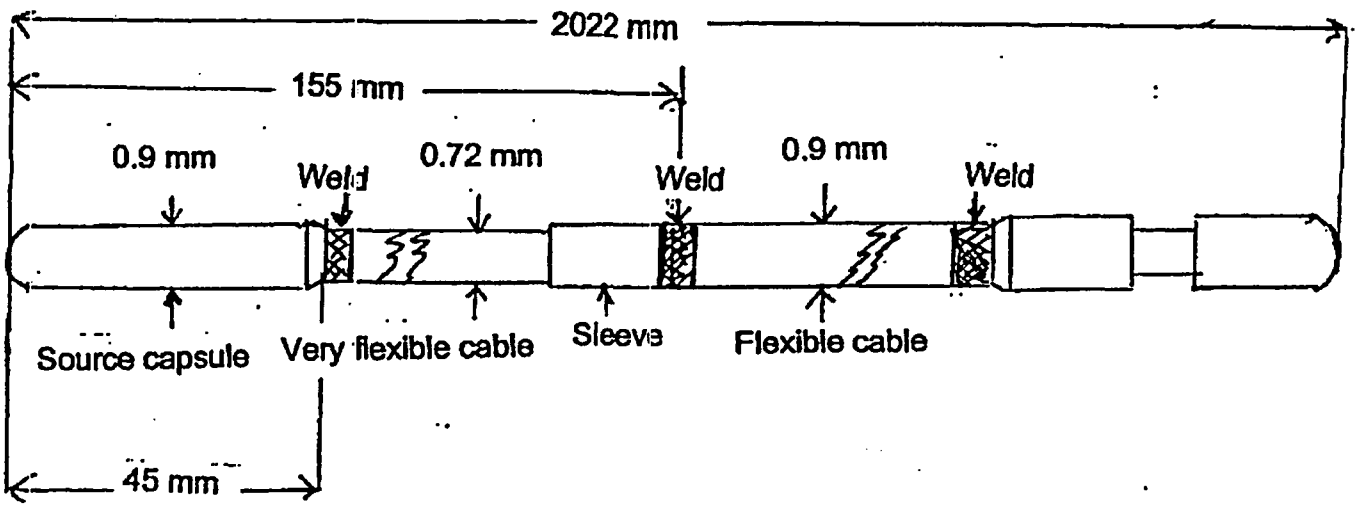


REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SOURCE
(AMENDED IN ITS ENTIRETY)

NO: MD-0497-S-107-S DATE: May 19, 2004

SOURCE TYPE: Medical Gamma Afterloading Source

Attachment 2 **Source Detail**



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO: MD-0497-D-108-S DATE: May 19, 2004

DEVICE TYPE: Remote Afterloading Brachytherapy

MODEL: 105.999

DISTRIBUTOR: Nucletron Corporation
8671 Robert Fulton Drive
Columbia, Maryland 21046

MANUFACTURER: Nucletron Engineering B.V.
Waardgelder 1
3905 TH Veenendaal
The NETHERLANDS

SEALED SOURCE MODEL DESIGNATION: Nucletron Model 105.002
(formerly known as Mallinckrodt catalog# DRN 07736)

Mallinckrodt Medical B.V.
Westerduinweg 3
NL-1755 LE Petten, The Netherlands
or
AEA Technology
40 North Avenue
Burlington, Massachusetts

ISOTOPE: Iridium-192

MAXIMUM ACTIVITY: 12 curies (444 GBq) one source. 13 curies (481 GBq) replacement source stored for decay to 12 curies at facility.

LEAK TEST FREQUENCY: Six (6) months

PRINCIPAL USE: (V) General medical use

CUSTOM DEVICE: _YES x NO

DEVICE TYPE: Remote Afterloading Brachytherapy Unit

DESCRIPTION:

The microSelectron-HDR Model 105.999, described in this registry, is similar to the device described in registry sheet MD-497-D-104-S with improvements primarily in the area of ergonomics and user interface. Model 105.999 is a remote controlled afterloading system for treatment of cancer by intraluminal, intracavity and interstitial brachytherapy. The unit eliminates radiation exposure normally received by hospital staff during treatments. The Treatment Control Unit and Treatment Control Station as described below, are designed to work with the Treatment Unit described in SS&D Registry Sheet MD-497-D-104-S and the new Treatment Unit (described below).

Model 105.999 consists of:

a. Treatment Unit
b. Treatment Control Panel (Control Box)
c. Treatment Control Station
d. Patient Applicators

a. Treatment Unit: The treatment unit contains the main safe for the iridium-192 source, dual drive mechanisms for the source and the check cable (allows the check cable to check the condition of the applicator), two stepper motors (one for the source and one for the check cable), an indexing system to index through eighteen (18) separate source channels, power supply and an electric head treatment adjuster (allows adjustment of treatment head height for different body sites). The treatment unit is mounted on wheels and will only operate when installed in an appropriately shielded room. **See Attachments 1-4.**

The electronic module in the treatment unit monitors the primary dwell time of programmed dwell positions and assures the accurate positioning of both the source cable and the check cable by using optical encoders which define the position of those drive cables. These optical encoders ensure that any discrepancies between the intended and actual positions of these cables will result in an immediate withdrawal of the drive cable.

The treatment unit head uses a mechanical drive, with an unique anti-kink storage mechanism and stepping motor, that eliminates all backlash by only stepping in a forward direction. The drive mechanism also enables the drive cable to be a constant diameter from the source back to the machine. Prior to the source application a check cable run (simulator run) is conducted to assure that the source can go through the applicator and make the correct steps. This system ensures a comparative accuracy between the simulator run and the source run of less then +/- 1 millimeter (mm) throughout the treatment.

DEVICE TYPE: Remote Afterloading Brachytherapy Unit

DESCRIPTION (Continued):

Treatment Unit (cont): In summary, improvements in the Treatment Unit (comparison with MD-497-D-104-S) include a more stable and movable platform for patient positioning, improvement of units center of gravity, use of annular structure for structural rigidity between the treatment safe optical coupler. The safe is now designed for up to 12 Ci and the Treatment Unit now has a built-in radiation detector which independently senses radiation levels.

b. Treatment Control Panel (Control Box): The Treatment Control Panel contains a microprocessor control with main timer and backup timer (checked by a second microprocessor). **See Attachment 5.**

c. Treatment Control Station: The user programmable functions are located in the Treatment Control Station. This console consists of a PC based graphics terminal which uses a window management program. All device programming functions are carried out at the Treatment Control Station, including default set-up parameters for the Treatment Unit and the data entry radioactive source specification.

The control unit enables 48 possible source treatment positions (or steps) of 0.25 centimeters (cm), 0.5 cm, or 1.0 cm and giving treatment lengths of 12 cm, 24 cm, or 48 cm. Variable dwell times for each source position can be programmed and displayed. The control unit can store and display up to 18 independent treatment channels with source positions and treatment times and is used with the 18 channel indexing system. The system can store multiple standard source configurations and times, which are automatically corrected for the decay of the iridium-192 source. In the case of main power failure, the system contains a battery backup which will maintain treatment data and return the source to the fully shielded position. A printer records all patient treatment data, source configurations and times.

d. Patient Applicator: The manufacturer provides conventional applicators for gynecological, intracavitary, interluminal and interstitial brachytherapy along with the appropriate adapters that fit into the front of the indexing unit. All connecting tubes are individually inserted and locked. The machine can not send out a source unless an applicator is properly connected. Every treatment by a live source is preceded by a check cable run to detect any blockage or constrictions to ascertain that the live source can move freely both out and back. If the check cable run does not move freely out and back, the treatment run is aborted and the source remains within the safe until all obstructions are removed.

e. Source:

The source, as described in SS&D Registry Sheet MD-497-S-107-S, is constructed of iridium-192 metal (source pellet dimensions .65 millimeters (mm) diameter, 3.6 mm length) which is singly encapsulated in a stainless steel (AISI 316L) cylindrical capsule (capsule dimensions 0.9 mm diameter, 4.5 mm length). The source is at one side hemispherical and the other side welded to a metal plug and metal flexible cable. At the other end of the cable a metal engraved tail is welded. The source cable diameter is 0.9 mm. The source tail end-piece is engraved with a unique serial number. See Attachment 6.

DEVICE TYPE: Remote Afterloading Brachytherapy Unit

LABELING:

An adhesive-backed metallic and electrical approval label is attached to the cover of the device, at the point where the electrical cable enters the device.

Two "Caution-Radioactive" labels with the radiation trefoil symbol and name of radionuclide, are secured to the treatment unit (one on the treatment unit head and other on the base). One self-adhesive label specifying the trade name and manufacture's name is attached to the Treatment Unit and to the Treatment Control Panel. **See Attachment 7.**

DIAGRAMS:
Attachment 1. Cutaway of Treatment Unit Head
Attachment 2. Cutaway View Treatment Unit Head
Attachment 3. Treatment Unit with Cutaway of Head
Attachment 4. Treatment Unit with Cutaway of Head
Attachment 5. Diagram of System
Attachment 6. Source Diagram
Attachment 7. Source and Device Labels

CONDITIONS OF NORMAL USE:

Model 105.999 is intended for, interluminal, interstitial, intracavitary and gynecological treatment of cancer using high dose rate gamma radiation. The patient may be treated as a hospital in-patient, a hospital or clinic out-patient or in a private medical office. In all cases both the patient and the Treatment Unit must be in a properly shielded room adequate to protect the general public and auxiliary personnel from unnecessary radiation exposure. The treatment procedure is identical to that of normal brachytherapy implants but with shorter treatment times.

The system must be installed in a shielded room where the temperature does not exceed 40°C or fall below 10°C and will be operated under the direction of a radiotherapist. The manufacturer's recommended frequency for replacing the source is three (3) months by a Nucletron engineer. Nucletron Corporation claims that Model 105.999 is designed to be transported from one location to another. This claim is supported by Nucletron Corporation's submission of test procedures and results from Wyle Laboratories which indicate that the unit has been subjected to and passed Type A package testing to meet the applicable DOT rules and regulations for the transportation of radioactive materials. Also, the distributor states that during transport the source will be maintained, at all times in the shielded position, via a "source transport lock" which is supplied by Nucletron Corporation.

DEVICE TYPE: Remote Afterloading Brachytherapy Unit

CONDITIONS OF NORMAL USE (Continued):

It is the distributor's opinion that, in order to ensure that the device is being used properly in the correct environment, all facilities that the device will be transported to will have a "permanent room setup." This setup should not be portable or temporary.

The anticipated catastrophic condition that might occur is fire. Normally hospitals, clinics, and private offices would be constructed to meet local and national fire regulations; however, the tungsten shielding in the Treatment Unit is deemed adequate for any predicted catastrophe. Additionally, the system is designed so that the patient can be quickly disconnected and the source stored in the shield in a matter of seconds.

PROTOTYPE TESTING:

Mallinckrodt Medical B.V. has tested the sources in accordance with ISO 2919 and ISO 1677 requirements. The testing was conducted under the consultation of the Ministry of Medical Investigation and Testing (BAM) located in Berlin, Germany. The source achieved classification designation ISO/C53211. The device was developed under ISO 9001 Quality Systems Requirements. The manufacturer indicates that the prototype was tested to conform to design specifications and that functional and safety aspects of the system (Alpha, Beta, Gamma format) were checked under normal and single fault conditions. New software for the device was tested and passed under the manufacturer's Treatment Console Software Test-Plan.

EXTERNAL RADIATION LEVELS:

When the main safe contains 12 Ci of iridium-192, the dose rates around the treatment unit are:

Distance	Exposure Levels
Surface	0.48 mR/hr (4.8μSv/hr)
5 cm	0.27 mR/hr (2.7μSv/hr)
30 cm	0.08 mR/hr (0.8 μSv/hr)
100 cm	0.02 mR/hr (0.2 μSv/hr)

DEVICE TYPE: Remote Afterloading Brachytherapy Unit for interstitial, intracavitary, interluminal and gynecological radiotherapy

MODEL: 105.999

QUALITY ASSURANCE AND CONTROL:

Model 105.999 has been tested for the life of the drive motors and the metal drive cable used to transfer the source. Nucletron states that the anticipated life of these components is greater than 10 years. Factory verification of all system functions and a burn-in test is conducted prior to shipment. For permanent installations Nucletron Corporation engineers conduct quality assurance safety testing at customer sites during device installation and source exchanges. Nucletron states that installation and quality assurance safety testing following the transportation and installation of the device into a "permanent room setup" must be completed in accordance with Nucletron's "Transportation Protocol." Complete information on the manufacturer's quality assurance program on the MicroSelectron-HDR afterloading brachytherapy unit has been submitted and deemed acceptable by Maryland.

DEVICE TYPE: Remote Afterloading Brachytherapy Unit

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

1. This device shall be distributed only to persons specifically licensed by the NRC or an Agreement State.

2. **The Nucletron model 105.999 remote gamma afterloading brachytherapy device exclusively utilizes the Nucletron Corporation Model 105.002 sealed source manufactured by Mallinckrodt Medical BV, Petten, Holland, and AEA Technologies, Inc., Burlington, MA.**

3. The source shall be leak tested at intervals not to exceed six (6) months using techniques capable of detecting 0.005 microcuries of removable contamination.

4. Handling, storage, use, transfer, and disposal is to be determined by the licensing authority. Because the sealed sources have high exposure rates, they must be installed and transferred only by experienced, trained and licensed personnel using adequate handling of equipment and procedures.

5. The device shall be installed and initially tested for proper operations of the source exposure mechanism, safety warning component labels, external radiation levels (both source exposed and source shielded) and leak tested at appropriate intervals previously stated on page one under "leak test frequency" by trained Nucletron service personnel or persons specifically licensed by an Agreement State or the NRC. Further, the reviewer should request documentation of training/experience of the service representative who will install and service the device.

6. The device shall be installed in a shielded room that has adequate interlocks and labeling to meet the requirements of COMAR 26.12.01.01, Part D, Section D.201, Section D.601 or comparable NRC or Agreement State Regulations.

7. The Nucletron Corporation HDR Model 105.999 has been tested to Type A package requirements. However, the device may only be used at appropriate locations as listed on a license issued by an Agreement State or the NRC. Following transport from one location to another, the device must be properly installed by persons specifically licensed by an Agreement State or the NRC, trained by a Nucletron Engineer and using Nucletron's "Transportation Protocol."

DEVICE TYPE: Remote Afterloading Brachytherapy Unit

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:, Continued

8. The source shall be locked into the shielded position using Nucletron Corporation's "source transport lock" during transport from one location to another.

9. This registration sheet and the information contained with the references shall not be changed without the written consent of the Maryland Department of the Environment.

SAFETY ANALYSIS SUMMARY:

1. This device is designed so that the radiation source will be withdrawn into the tungsten shielding if any alarm or failure condition arises.

2. If the treatment is interrupted for any reason the source is retracted into the safe in approximately 5 seconds.

3. It is impossible to send out the radiation sources unless an applicator is correctly connected, the door is closed, and the check cable run checks positively the condition of the applicator and the HDR system.

4. Model 105.999 has dual timer mechanism. The primary timer in the Treatment Unit counts the actual dwell timing. As soon as the source leaves the safe the secondary timer starts counting up. The trip level of the secondary timer (located in the Treatment Control panel) is set to the total treatment time plus twice the transfer time. If the source is not in the safe when the secondary timer reaches the trip level, an alarm is generated and the emergency stop circuit is activated.

5. In the event of complete failure of the system there is a hand-controlled winch which can withdraw the source in approximately 5 seconds.

6. In Model 105.999, the door interlock switch is directly wired to the Treatment Unit. In all circumstances, if the treatment room door is opened the radiation source will be withdrawn into the tungsten shielding .

7. The "source transport lock" is designed to maintain the source in the fully shielded position in the device even if the source becomes detached from the cable or the device; or the device is subjected to an unusual orientation.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO: MD-0497-D-108-S DATE: May 19, 2004

DEVICE TYPE: Remote Afterloading Brachytherapy Unit

SAFETY ANALYSIS SUMMARY:

Based on our review of the information and data submitted, we conclude that the Model 105.999 device designs are acceptable for licensing purposes. We conclude that this device will be expected to maintain containment integrity for both normal and accidental conditions which might occur during routine use.

REFERENCES:

The following supporting documents for the Model 105.998 are hereby made part of this registry document:

1. The Nucletron Corporation application for evaluation dated October 4, 1996.

2. SS&D sheets MD-497-D-104-S and MD-497-S-107-S.

3. Letters and attachments dated December 2, 1996 and December 30, 1996.

4. Letters and attachments dated February 6, 1997, August 12, 1997, November 24, 1997, January 9, 1998, and February 18, 1998.

5. Letters and attachments dated February 12, 1999, March 25, 1999, February 23, 2000, August 18, 2000, August 25, 2000, January 17, 2001, April 5, 2001, May 9, 2001, August 1, 2001, October 28, 2001, December 27, 2001, February 15, 2002, and April 22, 2003.

6. Letter dated April 22, 2003 and letter and attachments dated July 14, 2003.

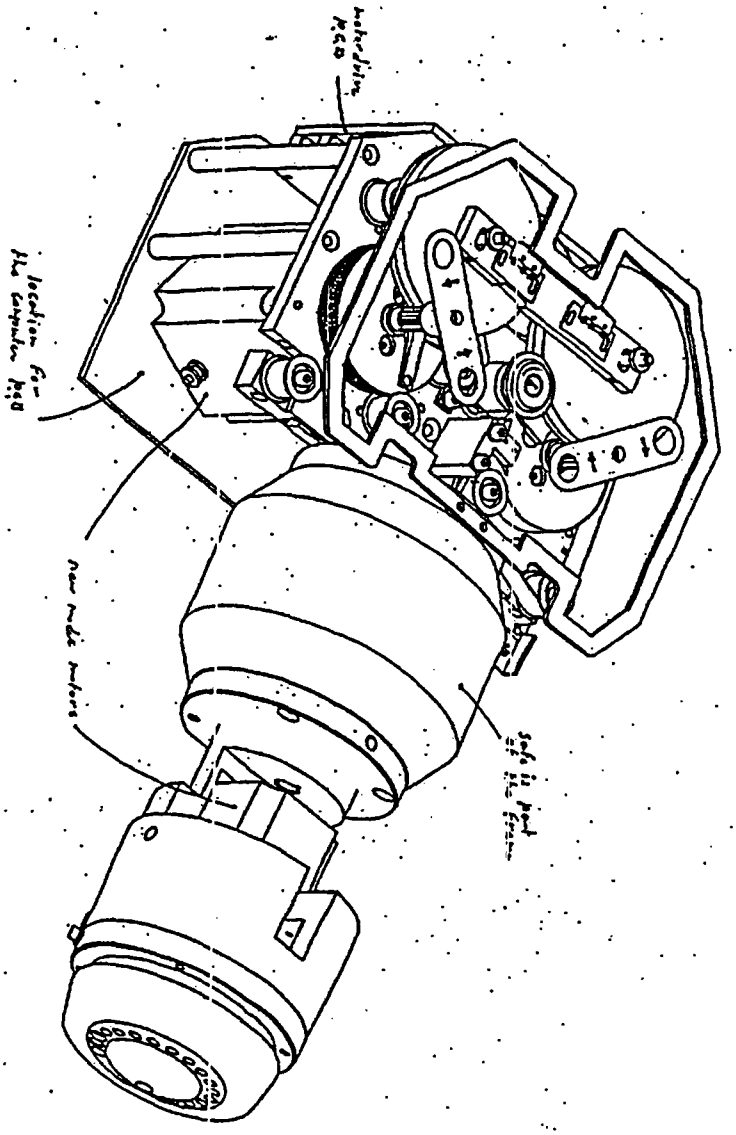
7. **Letter received from Nucletron Corporation on August 4, 2003, with BAM Approval Certificate D/0070/S-96 (Rev. 2), which adds AEA Technology as a manufacturer of this source.**

DATE: May 19, 2004 REVIEWED BY: Barbara J. Park
Barbara J. Park

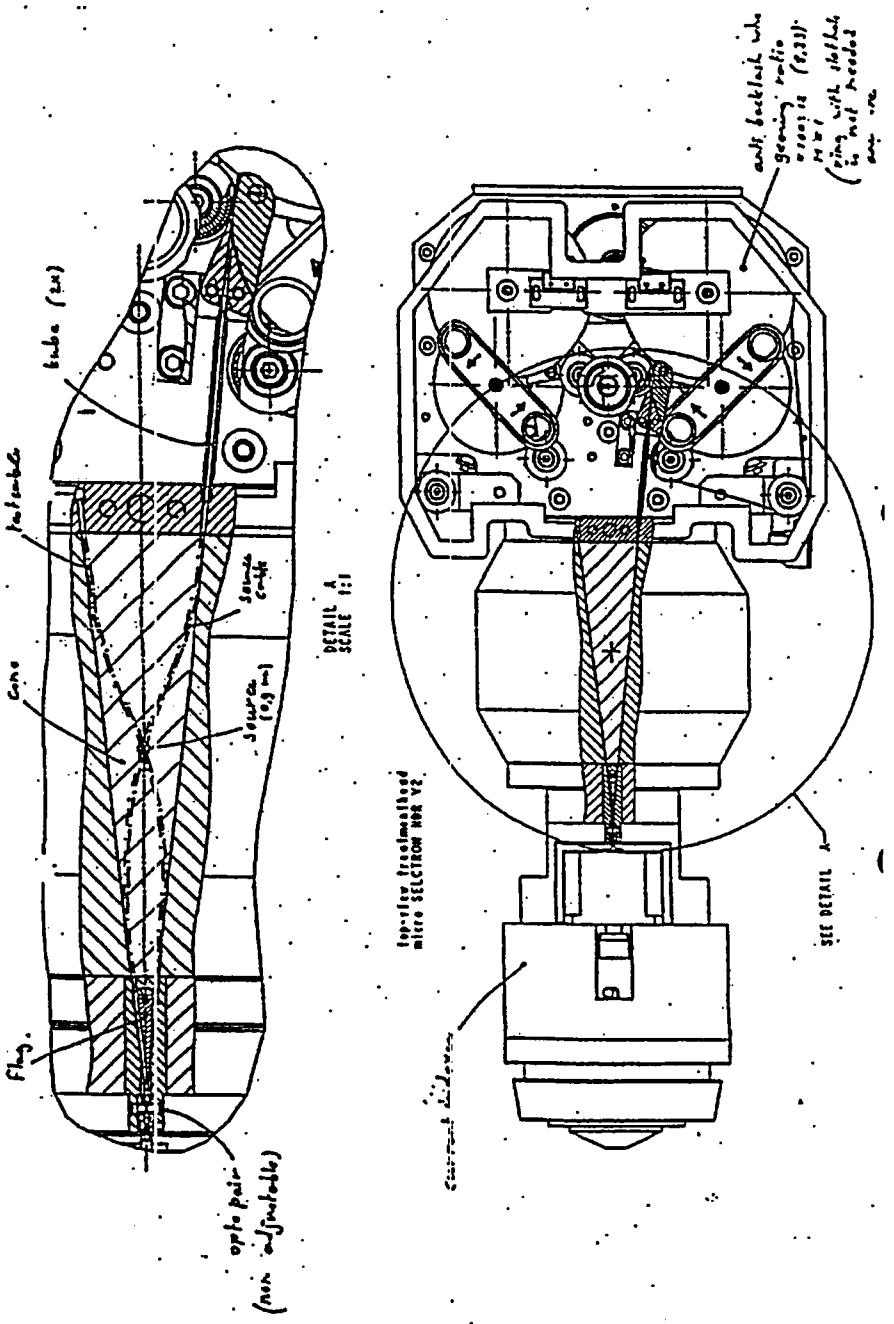
DATE: May 19, 2004 CONCURRENCE: Raymond E. Manley
Raymond E. Manley

ISSUING AGENCY:
Maryland Department of the Environment
Radiological Health Program
1800 Washington Boulevard
Baltimore, Maryland 21230

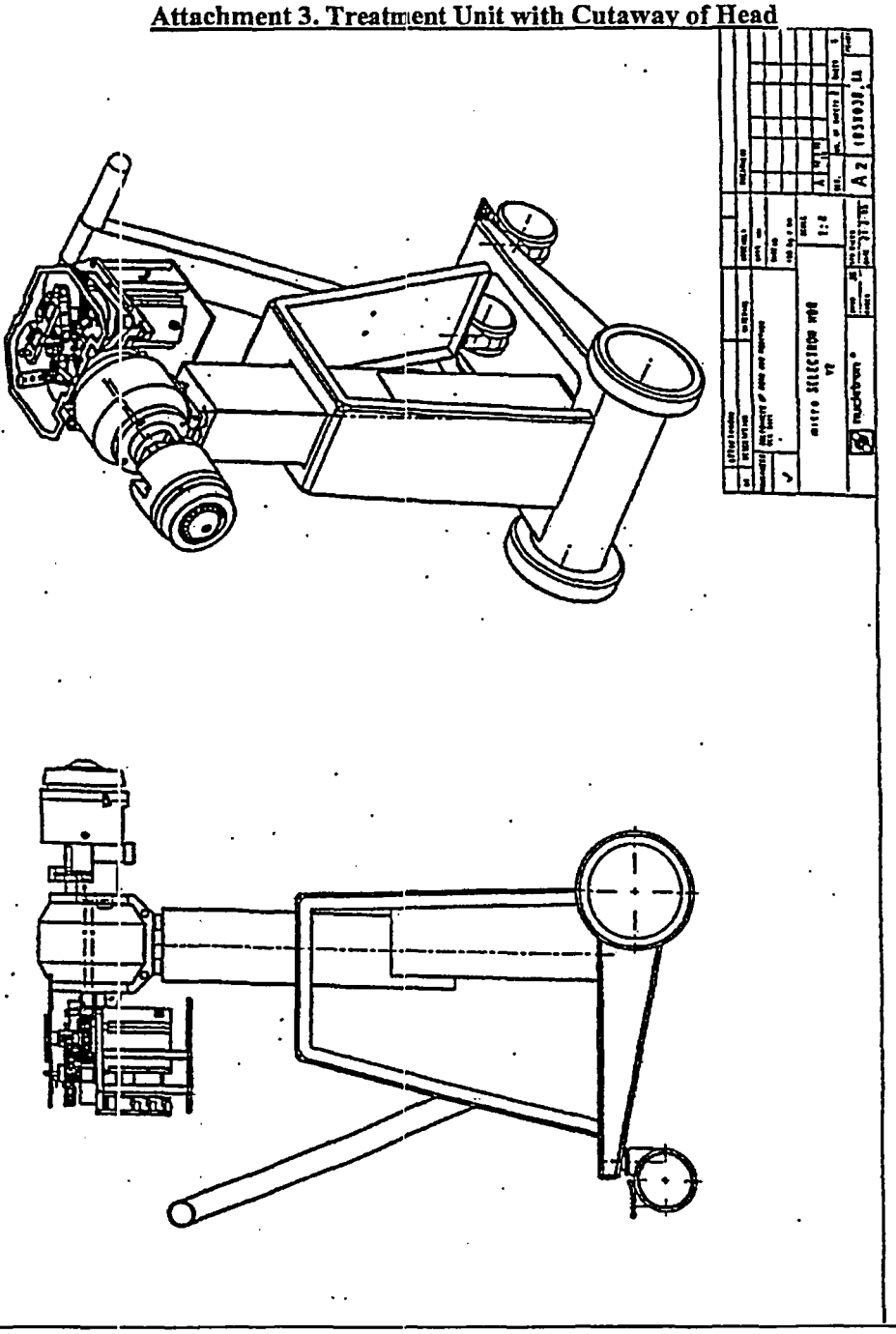
Attachment 1. Cutaway View of Treatment Unit Head



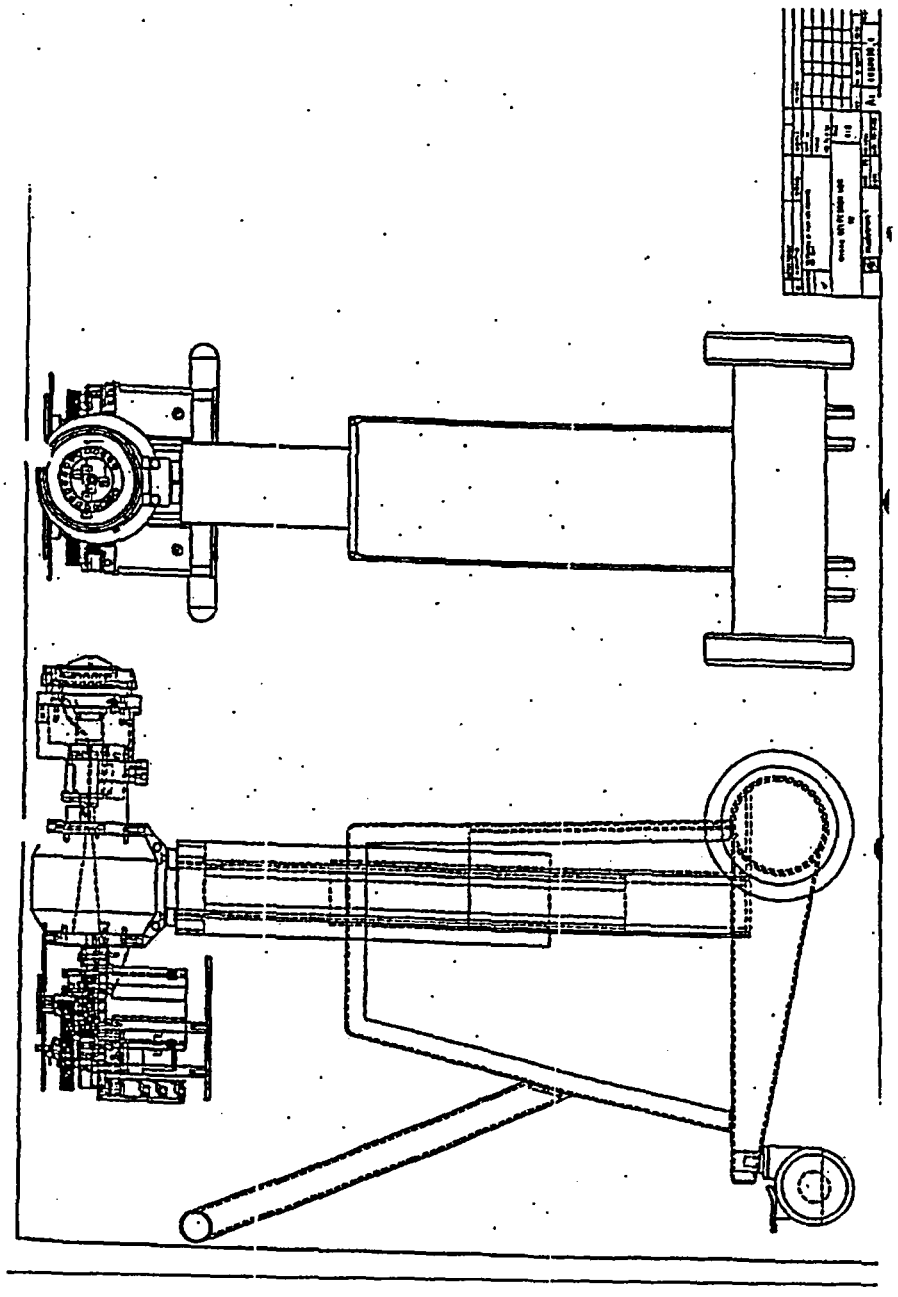
Attachment 2. Cutaway View Treatment Unit Head



Attachment 3. Treatment Unit with Cutaway of Head



Attachment 4. Treatment Unit with Cutaway View of Head



Attachment 5. Diagram of System

nucletron®

System Description

System Interconnections

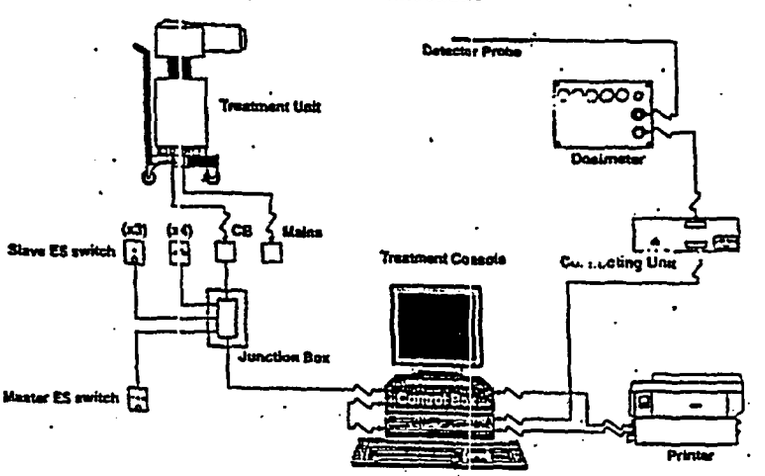


Figure 1-3 System Interconnection Diagram

The treatment unit is plugged into a wall-mounted connection box (Figure 1-3: CB). Data exchange between treatment unit and control box takes place via the junction box.

The junction box has also terminals for connecting:

- The master and the slave emergency stop switches.
- The door switch(es).
- A source-out of safe indicator (optional). This can be mounted near the door to the treatment room.
- The Control Box

The control box is connected to:

- The treatment console.
- The printer.
- The Junction Box

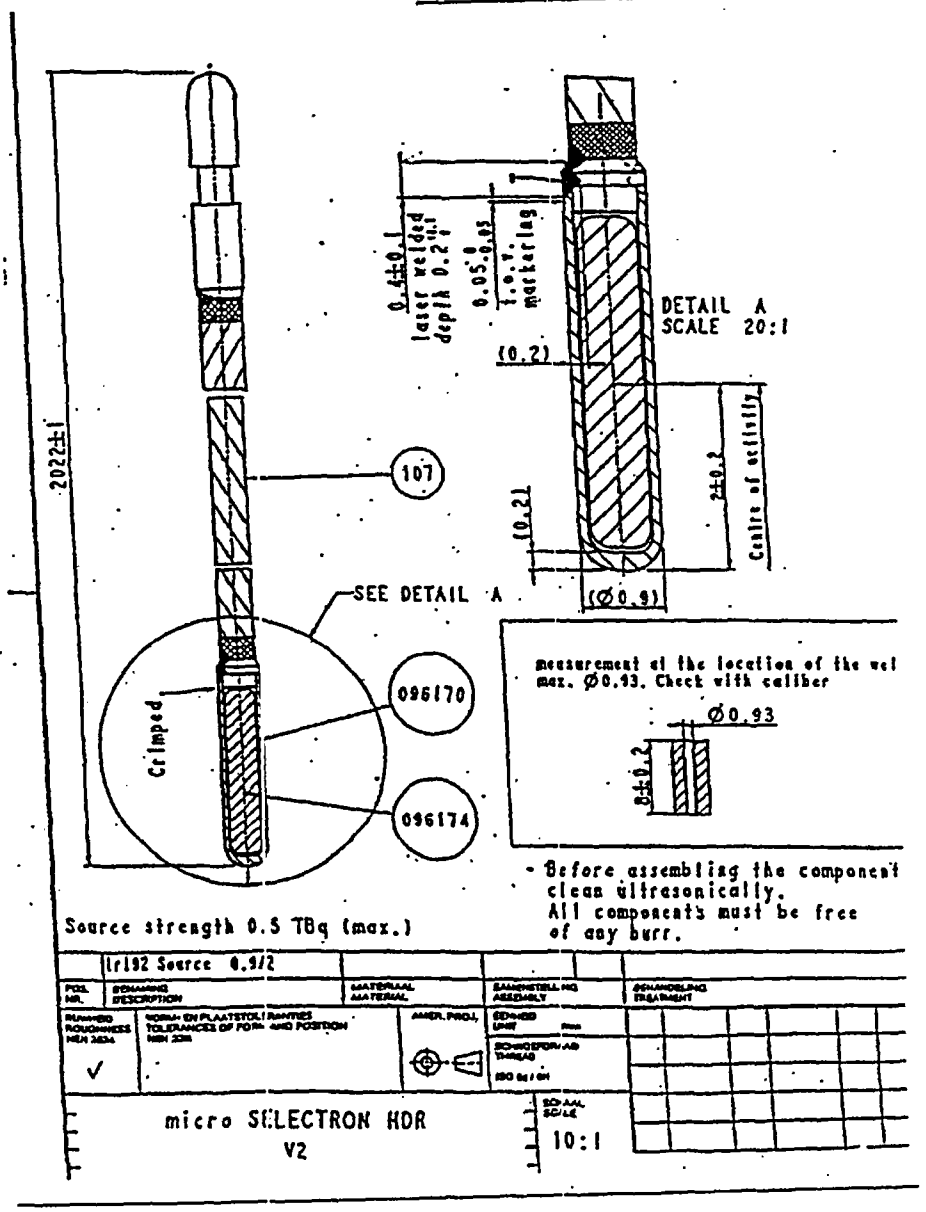
The treatment console is connected to:

- The printer.
- The in-vivo dosimeter (optional).
- The Control Box

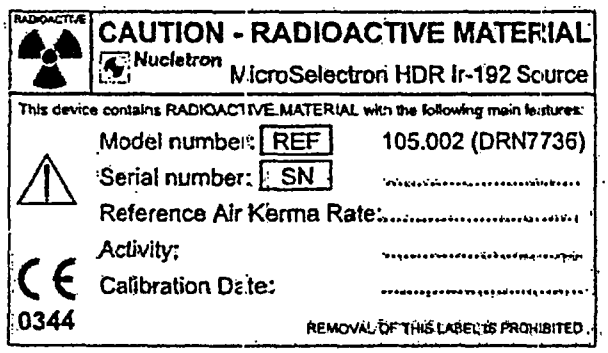
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

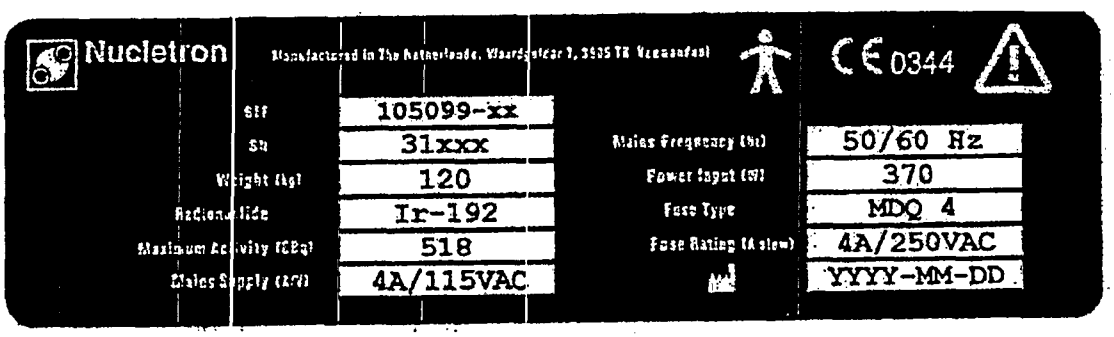
NO: MD-0497-D-108-S DATE: May 19, 2004

Attachment 6. Source Diagram



Attachment 7. Source and Device Labels





This is to acknowledge the receipt of your letter/application dated

2/24/2006, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 29-03297-01

☑ There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

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A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 138529.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader